



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,310	03/14/2001	Timothy E. Benson	00403.CP	3091

26813 7590 06/10/2002

MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER

GALITSKY, NIKOLAI M

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 06/10/2002

5
1
)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,310

Applicant(s)

BENSON ET AL.

Examiner

Nikolai M. Galitsky

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1631

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- | | |
|-----------|---|
| Group I | Claims 1-4 and 37-40, drawn to a glycosylated molecule or molecular complex of a human beta secretase binding pocket, classified in Class 530, subclass 300. If this Group is elected, than the below summarized species election is also required. |
| Group II | Claims 5-13 and 41-47, drawn to a scalable three dimensional configuration of points derived from structure listed in Table 1, classified in Class 702, subclass 19. If this Group is elected, than the below summarized species election is also required. |
| Group III | Claims 14, 15, 48, and 49, drawn to a machine-readable data storage medium, classified in Class 703, subclass 1. If this Group is elected, than the below summarized species election is also required. |

Art Unit: 1631

- Group IV Claims 16 and 50, drawn to a method for obtaining structural information about a molecule or a molecule complex of unknown structure, classified in Class 702, subclass 27.
- Group V Claims 17 and 51, drawn to a method for homology modeling a human beta secretase homolog, classified in Class 703, subclass 1.
- Group VI Claims 18-22, drawn to a computer-assisted method for identifying an inhibitor of a human beta secretase activity, classified in Class 703, subclass 2. If this Group is elected, than the below summarized species election is also required.
- Group VII Claims 23-26 and 52, drawn to a computer-assisted method for designing an inhibitor of a human beta secretase activity, classified in Class 703, subclass 1. If this Group is elected, than the below summarized species election is also required.
- Group VIII Claims 27-29 and 53, drawn to a computer-assisted method for designing an inhibitor of a human beta secretase activity *de novo*, classified in Class 703, subclass 1. If this Group is elected, than the below summarized species election is also required.
- Group IX Claims 31-33, drawn to a method making an inhibitor of a human beta secretase activity, classified in Class 435, subclass 69.1. If this Group is elected, than the below summarized species election is also required.

Art Unit: 1631

Group X Claims 34-36, drawn to an inhibitor of a human beta secretase activity, classified in Class 435, subclass 188. If this Group is elected, than the below summarized species election is also required.

Group XI Claims 54-76, drawn to a crystal of a human beta secretase and method for crystallizing a human beta secretase, classified in Class 435, subclass 4.

Group XII Claim 30, drawn to a method for synthesizing and assaying the potential inhibitor, classified in Class 435, subclass 25.

Group XIII Claims 77 and 78, drawn to a method of producing human beta secretase, classified in Class 435, subclass 325. If this Group is elected, than the below summarized species election is also required.

The inventions are distinct, each from the other because of the following reasons:

The inventions Group I and Group II are separate, patentably distinct products. The products are distinct both physically and functionally and have different use. For example, the molecule of Group I may find use as a drug, which is a distinct use as compared to a scalable three dimensional configuration of points of Group II. These Groups are also classified in different classes and subclasses.

The inventions of Group I and Group III are patentably distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the molecule or molecular complex of Group I is used in alternative inventions of Groups III and V, drawn to a machine-readable medium and a method

for homology modeling, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group IV are related as product and process of use. In the instant case the molecule or molecular complex of Group I is used in alternative inventions of Groups III and V, drawn to a machine-readable medium and a method for homology modeling, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group V are related as product and process of use. In the instant case the molecule or molecular complex of Group I may be used in the alternative inventions of Groups III and V, drawn to a machine-readable medium and a method for homology modeling, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group VI are related as product and process of use. In the instant case the molecule or molecular complex of Group I may be used in the alternative inventions of Groups III and VI, drawn to a machine-readable medium and a method for identifying an inhibitor, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the

Art Unit: 1631

coordinates of homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group VII are related as product and process of use. In the instant case the molecule or molecular complex of Group I is used in alternative inventions of Groups III and VI, drawn to a machine-readable medium and a method for designing an inhibitor, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group VIII are related as product and process of use. In the instant case the molecule or molecular complex of Group I is used in alternative inventions of Groups III and VI, drawn to a machine-readable medium and a method for designing an inhibitor, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group IX are related as product and process of use. In the instant case the molecule or molecular complex of Group I is used in alternative methods of Groups IV and IX, drawn to a method obtaining structural information and a method making an inhibitor, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions Group I and Group X are separate, patentably distinct. The products are distinct both physically and functionally and have different use. The inventions of Groups I and Group X are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups I the critical feature is a polypeptide; and for Group X the critical feature is an inhibitor. It is acknowledged that both products may use as a drug, however, the completely separate chemical types of the inventions of the polypeptide, and inhibitor Groups supports the undue search burden if both were examined together. These Groups are also classified in different classes and subclasses.

The inventions of Group I and Group XI are related as product and distinct product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process of group XI is directed to a particular a crystal of a human beta secretase and method for crystallization. The molecule of Group I can be used in the distinct processes of the inventions of Group VI (a method for identifying an inhibitor I) or in the distinct method of Group VII (a method for designing an inhibitor), or, alternatively, in a method for homology modeling (Group V).

The inventions of Group I and Group XII are related as product and process of use. In the instant case the molecule or molecular complex of Group I is used in alternative methods of Groups IV and IX, drawn to a method obtaining structural information and a method making an inhibitor, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a

Art Unit: 1631

homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The inventions of Group I and Group XIII are patentably distinct. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the molecule or molecular complex of Group I is used in alternative inventions of Groups III and V, drawn to a machine-readable medium and a method for homology modeling, respectively. In addition, the molecule or molecular complex of Group I can be used in a method of molecular replacement in x-ray crystallography to obtain the coordinates of a homologous structure, which is also a clearly distinct usage of a molecule or molecular complex coordinates.

The method of Group II and III are patentably distinct. The invention of Group III is drawn to a machine-readable data storage medium. The invention of Groups II, drawn to a scalable three dimensional configuration of points. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups II and IV are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of these Groups have different functions, different effects, and different modes of operation. The invention of Group IV, drawn for obtaining structural information about unknown structure by, for example, generates an x-ray

diffraction pattern from the crystallized molecule. The invention of Group II drawn to a scalable three dimensional configuration of points. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups II and V are patentably distinct. The method for homology modeling of a human beta secretase of Group V is not required in Group II.

The inventions of Groups II and VI are patentably distinct. The method for identifying or making an inhibitor of Group VI is not required in Group II.

The method of Group II and VII are patentably distinct. The method of Group VII is drawn to designing an inhibitor of a human beta secretase. The invention of Groups II is drawn to a scalable three dimensional configuration of points. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group II and VIII are patentably distinct. The invention of Group II is drawn to a scalable three dimensional configuration of points that is not required for the methods of Groups VIII.

The inventions of Groups II and IX, X are patentably distinct. The invention of Group II is drawn to a scalable three dimensional configuration of points that is not required for the inventions of Groups IX or X.

The method of Group II and XI are patentably distinct. The invention of Group XI is drawn to a crystal of a human beta secretase and method for crystallization. The invention of Groups II, drawn to a scalable three dimensional configuration of points. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups II and XII are patentably distinct. The invention of Group II is drawn to a scalable three dimensional configuration of points, that is not required for the invention of Groups XII for synthesizing and assaying the potential inhibitor.

The inventions of Groups II and XIII are patentably distinct. The invention of Group II is drawn to a scalable three dimensional configuration of points that is not required for the invention of Groups XIII for producing human beta secretase.

The inventions of Groups III and IV are independent. In the instant case, the different claimed inventions are independent inventions for a machine-readable data storage medium and obtaining structural information, which have different function; modes of operations and can produce different results.

The inventions of Groups III and V are patentably distinct. The invention of Group III is not required for identifying an inhibitor of Group V.

The inventions of Groups III and VI are patentably distinct. The invention of Group II is not required for designing an inhibitor of Group VI.

The inventions of Groups III and VII are patentably distinct. The invention of Group III is not required for making an inhibitor of Group VII.

The inventions of Groups III and VIII are patentably distinct. The methods of Groups VI-VIII are not required in Group III, or vice versa, because an inhibitor of a human beta secretase of Groups VI-VIII is not required for Group III.

The methods of Groups III and IX, X are patentably distinct. The invention of Group III is drawn to a machine-readable data storage medium that is not required for the inventions of Groups IX or X.

The inventions of Groups III and XI are patentably distinct. The inventions of Group III is drawn a machine-readable data storage medium, whereas in contrast Group XI is drawn to a crystal of a human beta secretase and method for crystallization. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group III and XII are patentably distinct. The invention of Group III is drawn to a machine-readable data storage medium that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group III and XIII are patentably distinct. The invention of Group III is drawn to a machine-readable data storage medium that is not required for the method of Group XIII for producing human beta secretase.

The inventions of Groups IV and V are patentably distinct. The invention of Group V is drawn to the method for homology modeling of a human beta secretase homolog, whereas in contrast Group IV is drawn to a method for obtaining unknown structural information. The methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups IV and VI are patentably distinct. The invention of Group IV is drawn to the method for obtaining unknown structural information, whereas in contrast Group VI is drawn to a method for identifying an inhibitor of a human beta secretase activity. The methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups IV and VII are patentably distinct. The invention of Group IV is drawn to the method for obtaining unknown structural information, whereas in contrast Group VII is drawn to a method for designing an inhibitor of a human beta secretase activity. The

methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups IV and VIII are patentably distinct. The method of Group VIII is not required in Group IV, or vice versa, because an inhibitor of a human beta secretase of Group VIII is not required for Group IV.

The methods of Groups IV and IX, X are patentably distinct. The invention of Group IV is a method for obtaining unknown structural information that is not required for the inventions of Groups IX or X.

The inventions of Groups IV and XI are patentably distinct. The methods of these Groups have different functions, different effects, and different modes of operation.

The method of Group IV and XII are patentably distinct. The invention of Group IV is drawn to the method for obtaining structural information that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group IV and XIII are patentably distinct. The invention of Group IV is drawn to the method for obtaining structural information that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Groups V and VI are patentably distinct. The invention of Group V is drawn to the method for homology modeling a human beta secretase homolog, whereas in contrast Group VI is drawn to a method for identifying an inhibitor of a human beta secretase. The methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Groups V and VII are patentably distinct. The invention of Group V is drawn to the method for homology modeling a human beta secretase homolog, whereas in contrast Group VII is drawn to a method for designing an inhibitor of a human beta secretase. The methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group V and Group VIII are related as distinct method of homology modeling and a method of designing an inhibitor. These Groups have different functions, different effects, and different modes of operation.

The methods of Groups V and IX, X are patentably distinct. The invention of Group V is directed to a method for homology modeling that is not required for the inventions of Groups IX or X.

The inventions of Groups V and XI are patentably distinct. The inventions of these Groups have different functions, different effects, and different modes of operation.

The method of Group V and XII are patentably distinct. The invention of Group V is directed to a method for homology modeling, that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group V and XIII are patentably distinct. The invention of Group V is directed to a method for homology modeling, that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Groups VI and VII are patentably distinct. The invention of Group VI is drawn to the method for designing an inhibitor of a human beta secretase activity, whereas in contrast Group VII is drawn to a method for making an inhibitor of a human beta secretase. The

Art Unit: 1631

methods of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group VI and Group VIII are related as distinct methods of identifying and designing an inhibitor of a human beta secretase activity *de novo*. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups VI and IX, X are patentably distinct. The invention of Group VI comprises screening a library of chemical entities, that not require for the inventions of Groups IX or X.

The inventions of Groups VI and XI are patentably distinct. The methods of these Groups have different functions, different effects, and different modes of operation.

The method of Group VI and XII are patentably distinct. The invention of Group VI comprises screening a library of chemical entities that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group VI and XIII are patentably distinct. The invention of Group VI comprises screening a library of chemical entities that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Group VII and Group VIII are related as distinct methods of designing an inhibitor and designing an inhibitor of a human beta secretase activity *de novo*. The inventions of these Groups have different functions, different effects, and different modes of operation.

The methods of Groups VII and IX, X are patentably distinct. The invention of Group VII is directed to practice the set structural coordinates that are not required for the inventions of Groups IX or X.

The inventions of Groups VII and XI are patentably distinct. The invention of Group VII is drawn to the method making an inhibitor of a human beta secretase activity, whereas in contrast Group XI is drawn to, for example, a method for crystallizing an of a human beta secretase. The methods of these Groups have different functions, different effects, and different modes of operation.

The method of Group VII and XII are patentably distinct. The invention of Group VII is directed to practice the set structural coordinates that are not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group VII and XIII are patentably distinct. The invention of Group VII is directed to practice the set structural coordinates, the method of Group VIII and XII are patentably distinct. The invention of Group VIII is drawn to the method designing an inhibitor of a human beta secretase activity that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Group VIII and Group IX are related as distinct methods of designing an inhibitor and making an inhibitor of a human beta secretase activity. The inventions of these Groups have different functions, different effects, and different modes of operation.

The inventions of Group VIII and Group X are related as distinct method of designing and product. The inventions of Group X is drawn to an inhibitor of a human beta secretase activity that can be practiced as a drug, which is a distinct practice as compared to a method for designing of Group VIII.

The inventions of Groups VIII and XI are patentably distinct. The invention of Group VIII is drawn to the method designing an inhibitor of a human beta secretase activity, whereas in

Art Unit: 1631

contrast Group XI is drawn to, for example, a method for crystallizing a human beta secretase.

The methods of these Groups have different functions, different effects, and different modes of operation.

The method of Group VIII and XII are patentably distinct. The invention of Group VIII is drawn to the method designing an inhibitor of a human beta secretase activity that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group VIII and XIII are patentably distinct. The invention of Group VIII is drawn to the method designing an inhibitor of a human beta secretase activity that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Group IX and Group X are related as distinct method making an inhibitor and product, respectively. The invention of Group X is drawn to an inhibitor of a human beta secretase activity that can be practiced as a drug. These Groups have different functions, different effects, and different modes of operation.

The inventions of Groups IX and XI are patentably distinct. The invention of Group IX is drawn to the method making an inhibitor of a human beta secretase activity, whereas in contrast Group XI is drawn to, for example, a method for crystallizing an of a human beta secretase. The methods of these Groups have different functions, different effects, and different modes of operation.

The method of Group IX and XII are patentably distinct. The invention of Group IX is drawn to the method making an inhibitor of a human beta secretase activity that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group IX and XIII are patentably distinct. The invention of Group IX is drawn to the method making an inhibitor of a human beta secretase activity that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Group X and Group XI are patentably distinct. The products are distinct both physically and functionally and have different use. The invention of Group XI is drawn to a crystal and the invention of Group X, for example, is drawn to the inhibitor of a human beta secretase activity. These Groups are also classified in different classes and subclasses.

The method of Group X and XII are patentably distinct. The invention of Group X is drawn to the method making an inhibitor of a human beta secretase activity that is not required for the method for synthesizing and assaying the potential inhibitor of Groups XII.

The method of Group X and XIII are patentably distinct. The invention of Group X is drawn to the method making an inhibitor of a human beta secretase activity that is not required for the method of Groups XIII for producing human beta secretase.

The inventions of Group XI and Group XII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process of group XI is directed to a particular a crystal of a human beta secretase and method for crystallization. The potential inhibitor of Group XII can be used in the distinct processes of the inventions of Group VI (a

Art Unit: 1631

method for identifying an inhibitor I) or in the distinct method of Group VII (a method for designing an inhibitor), or, alternatively, in a method for homology modeling (Group V).

The method of Group XI and XIII are patentably distinct. The invention of Group XI is drawn to a method for crystallizing an of a human beta secretase that is not required for the method of Groups XIII for producing human beta secretase.

The method of Group XII and XIII are patentably distinct. The method of Group XII is drawn to a method for synthesizing and assaying the potential inhibitor. The invention of Group XIII is drawn to a method for producing human beta secretase. The inventions of these Groups have different functions, different effects, and different modes of operation.

All Groups would require a distinct and different search with minimal overlap thus documenting the undue search burden of searching.

SPECIE ELECTION REQUIREMENT FOR GROUPS I-III, VI - X and XIII:

This application contains claim directed to the following patentably distinct species of the claimed invention: These species are distinct because they each add a feature to the methods searching for binding pocket or compositions with different structures and distinct functions which each would require a separate and burdensome search to add to the search for the basic detection molecule as defined above.

Groups I-II:

Specie A-1: Table 5;

Specie A-2: Table 6;

Specie A-3: Table 7.

Group III:

Art Unit: 1631

Specie B-2: Table 5;

Specie B-3: Table 6.

Groups VI-X:

Specie C-1: an inhibitor of a human beta secretase activity;

Specie C-2 a composition of a human beta secretase activity;

Specie C-3 a pharmaceutical composition of a human beta secretase activity.

Group XIII:

Specie D-1: a mammalian cell line;

Specie D-2: a insect cell line.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1631

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, the specie elections for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 8:30 A.M. to 5 P.M.

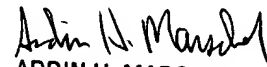
Art Unit: 1631

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 07, 2002

NMG


ARDIN H. MARSCHEL
PRIMARY EXAMINER